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10/647,449

08/25/2003

Manne Satyanarayana Reddy

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EXAMINER

CHANG, CELIA C

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/647,449
Filing Date: August 25, 2003
Appellant(s): REDDY ET AL.

Milagros A Cepeda
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the supplemental appeal brief filed Feb. 1, 2008 appealing from the Office action mailed Nov. 18, 2007 and Dec. 7, 2007.

(1) Real Party in Interest

Same as stated in the examiner's answer and incorporated by reference.

(2) Related Appeals and Interferences

Same as stated in the examiner's answer and incorporated by reference.

(3) Status of Claims

Same as stated in the examiner's answer and incorporated by reference.

(4) Status of Amendments After Final

Same as stated in the examiner's answer and incorporated by reference.

(5) Summary of Claimed Subject Matter

Same as stated in the examiner's answer and incorporated by reference.

(6) Grounds of Rejection to be Reviewed on Appeal

Same as stated in the examiner's answer and incorporated by reference.

(7) Claims Appendix

Same as stated in the examiner's answer and incorporated by reference.

(8) Supplemental Evidence Relied Upon for additional argument

Zhang et al. "Racemic species of sodium ibuprofen: characterization and polymorphic relationship" J. Pharm. Science 92(7) p.1356-1366 (2003)

Fasel et al. "Amplification of chirality in two dimensional enantiomorphous lattices" Nature 26 January (2006) p.439-452

Yokota et al. "Chiral separation by crystal size difference" CA143:60207 (2004).

(9) Grounds of Rejection

Same as stated in the examiner's answer and incorporated by reference.

(10) Response to Additional Argument

The gist of appellants' argument is that the prior art is crystal form of a racemate while the instant claims are drawn to crystal form of an enantiomer.

It is the Examiner's position that:

Appellants' allegation that ".....racemic regaglinide which is a "different chemical compound" and "...the disclosure of a polymorph of a racemic compound does not anticipates claims to a polymorph of an enantiomer" are misleading.

Insofar as the molecular formula is concerned, racemic compound and enantiomers are the same chemical identity with only difference in optical property. Therefore, they are not different chemical compounds but the same pure substance of the molecular formula.

Art Unit: 1600

Further, it is understood by one having ordinary skill in the crystal art that racemic crystals are well known to be either (i) made of physical mixture of the R-crystal and S-crystal (homochiral crystals) which are separable by mechanical means (see Fasel et al. and Yokota et al.); or (ii) made of racemate unit, i.e 1-R and 1-S pair or less ordered ratio (heterochiral crystals, the unit cells are made of both enantiomer, such as ibuprofen, see Zhang et al).

If the racemic crystals belong to phenomena (i), then, the party that owns the mixture owns both the R-crystal and the S-crystal since they are mere physical/mechanical coexisted crystals. If the racemic crystals belong to phenomena (ii), then the crystalline properties of the racemate will be differentiated from each S-crystal or R-crystal since they are made of different “unit cell”.

During examination and factual finding of the prior art, the examiner has compared carefully all the detailed parts among the “voluminous specification” called by the Appellants, and evidenced that identical IR was found between the IR depending claims and the prior art repaglinide form A with IR of fig. 4. Since IR of enantiomer would differentiate from IR of racemate (see Baumann et al. of record and explanation on p.9 examiner’s answer, 12/07/07), the identical IR finds anticipation of the specific claims. Just because Grell I calls it form A repaglinide and Appellants called the same product (S) repaglinide-Form III, does not provide sufficient evidence that the same IR of Grell I and the instant claim are different products. Many laboratories employ different nomenclature for polymorphs. Appellants provided mere arguments that they used different nomenclature without factual evidence that the two “products” having the same IR, are actually different. Please note that the 102 rejection is limited to those claims dependent on IR identification.

Based on the above evidence and understanding of the crystalline art, one having ordinary skill would recognized that phenomena (i) was the situation and the discrepancies among other physical measurements can be the result of not picking the interfering R-crystal from the S-crystal. The 103(a) rejection is proper since the difference in “other” physical measurement is the apparent result of not sieving Grell I’s crystal before taking such measurements. Therefore, Grell I is in possession of the claimed crystal, irrespective of how it was made, just not in its picked and sieved better quality. Purer or better quality is prima facie obvious, especially, the process of improvement is mechanical.

Art Unit: 1600

Contrary to Appellants allegation, the instant case is different from the Buchi case because clear and factual evidence has been made of record. The examiner has made detailed analysis of the scope of the claims and separated the one reading on identical IR and the claims employing variation of measurements because of obvious lesser quality specimen. Therefore, has met the burden required by law in the rejections. (Please note that the examiner provided evidence using the Fasel, Zhang or Yokota because they provide comprehensive description of the prior art which covered, as recited in the reference section, dates from 1848 to date)

The examiner, however, does not hold material or data to ascertain under what condition is phenomena (i) operating for repaglinide. However, with such prudent evidence in the record based on specific scientific literature and understanding by their skilled scientist authors, the burden has clearly been shifted to the Appellants who are the only holder of such material and data in providing evidence supporting or obviating the rejection.

(11) Related Proceeding(s) Appendix

Same as stated in the examiner's answer and incorporated by reference.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
/Celia Chang/
Primary Examiner, Art Unit 1625

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625

/Christopher S. F. Low/
Acting Director of Technology Center 1600